# Consultant year-end index

**VOLUME 23, JANUARY-DECEMBER 1983**

## INDEX TO MAJOR SUBJECTS


**Acne**, current therapeutic recommendations. Whiting DA. 83 Nov 49.
**Adolescence**, diagnosis of acute kidney failure. McCrory WW. 83 March 167.
homosexuality, 10 don'ts for parents. Mead BT. 83 April 107.
JRA diagnosis. Waring NP, DeShazo RD. 83 May 93.
pregnancy, risks of complications. Green KW. 83 May 187.
**Aged**, activity best medicine. Bortz WM. 83 Jan 304.
diabetes mellitus, diagnosis and management. Granner DK. 83 April 53.
hearing loss. Katz AE. 83 May 59.
heart murmurs, causes in the elderly. Ewy GA. 83 March 151.
**Agranulocytosis**, neutropenia in children and adults. Oski FA. 83 Jan 93.
**Air pollution**, high cost of (editorial opinion). Mohler JG. 83 June 260.
**Alcoholism**, recognizing progressive symptomatology. Mooney AL. 83 May 171.
**Allergens**, determination by patch testing. Maibach HI. 83 April 201.
**Alopecia**, current management. Headington JT. 83 Aug 137.
**Ambulatory care**, air travel, when it's contraindicated. Cowen MN. 83 April 177.
**Anemia**, of chronic disease. Brown EB. 83 Nov 235.
lab values in elderly (Brf Consult). Siegel F, Coodley E. 83 Feb 137.
**Anesthetic**, insomnia due to? (Brf Consult). Maxmen JS, Carron H. 83 June 45.
**Angina pectoris**, variant, diagnosis and management. McAuley BJ, Ginsburg R. 83 June 166.
**Angiocardiography**, when it is needed after MI. Marpole DGF. 83 March 224.
**Antibiotics**, isoniazid therapy (Brf Consult). Jay S. 83 Aug 209.
penicillin and rash (Brf Consult). Sullivan TJ. 83 Feb 225.
which to choose for a hospital pharmacy? (Brf Consult). Holloway WJ, Palmer DL. 83 Jan 241.
**Antibodies, monoclonal**, clinical applications. Mitchell MS. 83 May 127.
**Anticoagulants**, use in stroke therapy (Brf Consult). Gregoratos G. 83 Feb 300.
**Anxiety disorders**, panic attacks. Anderson RO. 83 Aug 177.
**Aortic coarctation.** See **Clinical Case** No. 101. 83 Jan 248.
**Arm injuries**, management. Lombardo JA. 83 Oct 143.
**Arrhythmia**, caused by sleep disorders. Guilleminault C, Mondini S. 83 July 193.
**Arthritis, juvenile rheumatoid**, diagnosis. Waring NP, DeShazo RD. 83 May 93.
**Ascariasis**, therapy for complicated and uncomplicated infections. Beutel WD, Allison JG. 83 July 213.
**Asthma**, diagnosis and treatment. Kandel G, Aberman A. 83 June 143.
pulmonary function testing in office. Ramsdell JW. 83 April 310.
**Athletic injuries**, cycling injuries, prevention. Kulund DN. 83 June 83.
promoting safer play in football and basketball. Moyer RA. 83 Nov 81.
**Autopsy**, its benefits. Anderson RE. 83 April 256.
**Basal ganglia diseases**, parkinsonism and tardive dyskinesia. Stewart RM. 83 June 51.
**Behavior**, investigating psychogenic breathlessness. Howell JBL. 83 Nov 151.
short-circuiting family violence. Arnold JF. 83 July 204.
**Bites and stings**, from marine animals. Ratzan RM, Correia CJ, Cardoni AA. 83 Aug 29.
wound care for animal bites. Wingert WA. 83 Feb 159.
**Bladder neoplasms**, diagnosis and treatment. Paulson DF. 83 Sept 151.
**Breast neoplasms**, biopsy pitfalls, proper care. Ames FC. 83 March 95.
follow-up procedure (Brf Consult). Bisel HF, Ames FC. 83 July 65.
**Breath tests**, in GI and liver disorders. King CE, Toskes PP. 83 Nov 117.
**Brief Consultations**
Amitriptyline for chronic pain. Thurman BH. 83 Dec 94.
Are tricyclics cardiotoxic? Patterson WM. 83 Sept 249.
Breast cancer follow-up. Bisel HF, Ames FC. 83 July 65.
Cerebral stroke in a young man. Sherman DE. 83 April 265.
Close watch on quinidine-digoxin interaction. Bigger JT Jr. 83 June 182.
Coma, diabetes, hypotension: a management ordeal. Whitehouse FW. 83 April 147.
Could insomnia be due to anesthesia? Maxmen JS, Carron H. 83 June 45.
Did drugs or oxygen induce pulmonary edema? Wolinsky H. 83 July 147.
Dreams of violence. Reid WH. 83 March 109.
Gauging the need for sleep. Carskadon MA, Dement WC. 83 Nov 296.
Her kidneys are fine but why the hyperphosphatemia? Manning RT. 83 Feb 269.
A historic look at homeopathy. Barrett S. 83 Oct 173.
Infectious diarrhea in pregnancy. Ravdin JI. 83 March 145.
Isoniazid therapy. Jay S. 83 Aug 209.
Labyrinthian disorder? Raskind R, Smith RW. 83 March 181.
Lidocaine during MI? Cohen SI. 83 Oct 247.
Lung cancer and headache. Marsh JC. 83 Nov 143.


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## INDEX TO MAJOR SUBJECTS


**Acne**, current therapeutic recommendations. Whiting DA. 83 Nov 49.
**Adolescence**, diagnosis of acute kidney failure. McCrory WW. 83 March 167.
homosexuality, 10 don'ts for parents. Mead BT. 83 April 107.
JRA diagnosis. Waring NP, DeShazo RD. 83 May 93.
pregnancy, risks of complications. Green KW. 83 May 187.
**Aged**, activity best medicine. Bortz WM. 83 Jan 304.
diabetes mellitus, diagnosis and management. Granner DK. 83 April 53.
hearing loss. Katz AE. 83 May 59.
heart murmurs, causes in the elderly. Ewy GA. 83 March 151.
**Agranulocytosis**, neutropenia in children and adults. Oski FA. 83 Jan 93.
**Air pollution**, high cost of (editorial opinion). Mohler JG. 83 June 260.
**Alcoholism**, recognizing progressive symptomatology. Mooney AL. 83 May 171.
**Allergens**, determination by patch testing. Maibach HI. 83 April 201.
**Alopecia**, current management. Headington JT. 83 Aug 137.
**Ambulatory care**, air travel, when it's contraindicated. Cowen MN. 83 April 177.
**Anemia**, of chronic disease. Brown EB. 83 Nov 235.
lab values in elderly (Brf Consult). Siegel F, Coodley E. 83 Feb 137.
**Anesthetic**, insomnia due to? (Brf Consult). Maxmen JS, Carron H. 83 June 45.
**Angina pectoris**, variant, diagnosis and management. McAuley BJ, Ginsburg R. 83 June 166.
**Angiocardiography**, when it is needed after MI. Marpole DGF. 83 March 224.
**Antibiotics**, isoniazid therapy (Brf Consult). Jay S. 83 Aug 209.
penicillin and rash (Brf Consult). Sullivan TJ. 83 Feb 225.
which to choose for a hospital pharmacy? (Brf Consult). Holloway WJ, Palmer DL. 83 Jan 241.
**Antibodies, monoclonal**, clinical applications. Mitchell MS. 83 May 127.
**Anticoagulants**, use in stroke therapy (Brf Consult). Gregoratos G. 83 Feb 300.
**Anxiety disorders**, panic attacks. Anderson RO. 83 Aug 177.
**Aortic coarctation.** See **Clinical Case** No. 101. 83 Jan 248.
**Arm injuries**, management. Lombardo JA. 83 Oct 143.
**Arrhythmia**, caused by sleep disorders. Guilleminault C, Mondini S. 83 July 193.
**Arthritis, juvenile rheumatoid**, diagnosis. Waring NP, DeShazo RD. 83 May 93.
**Ascariasis**, therapy for complicated and uncomplicated infections. Beutel WD, Allison JG. 83 July 213.
**Asthma**, diagnosis and treatment. Kandel G, Aberman A. 83 June 143.
pulmonary function testing in office. Ramsdell JW. 83 April 310.
**Athletic injuries**, cycling injuries, prevention. Kulund DN. 83 June 83.
promoting safer play in football and basketball. Moyer RA. 83 Nov 81.
**Autopsy**, its benefits. Anderson RE. 83 April 256.
**Basal ganglia diseases**, parkinsonism and tardive dyskinesia. Stewart RM. 83 June 51.
**Behavior**, investigating psychogenic breathlessness. Howell JBL. 83 Nov 151.
short-circuiting family violence. Arnold JF. 83 July 204.
**Bites and stings**, from marine animals. Ratzan RM, Correia CJ, Cardoni AA. 83 Aug 29.
wound care for animal bites. Wingert WA. 83 Feb 159.
**Bladder neoplasms**, diagnosis and treatment. Paulson DF. 83 Sept 151.
**Breast neoplasms**, biopsy pitfalls, proper care. Ames FC. 83 March 95.
follow-up procedure (Brf Consult). Bisel HF, Ames FC. 83 July 65.
**Breath tests**, in GI and liver disorders. King CE, Toskes PP. 83 Nov 117.
**Brief Consultations**
Amitriptyline for chronic pain. Thurman BH. 83 Dec 94.
Are tricyclics cardiotoxic? Patterson WM. 83 Sept 249.
Breast cancer follow-up. Bisel HF, Ames FC. 83 July 65.
Cerebral stroke in a young man. Sherman DE. 83 April 265.
Close watch on quinidine-digoxin interaction. Bigger JT Jr. 83 June 182.
Coma, diabetes, hypotension: a management ordeal. Whitehouse FW. 83 April 147.
Could insomnia be due to anesthesia? Maxmen JS, Carron H. 83 June 45.
Did drugs or oxygen induce pulmonary edema? Wolinsky H. 83 July 147.
Dreams of violence. Reid WH. 83 March 109.
Gauging the need for sleep. Carskadon MA, Dement WC. 83 Nov 296.
Her kidneys are fine but why the hyperphosphatemia? Manning RT. 83 Feb 269.
A historic look at homeopathy. Barrett S. 83 Oct 173.
Infectious diarrhea in pregnancy. Ravdin JI. 83 March 145.
Isoniazid therapy. Jay S. 83 Aug 209.
Labyrinthian disorder? Raskind R, Smith RW. 83 March 181.
Lidocaine during MI? Cohen SI. 83 Oct 247.
Lung cancer and headache. Marsh JC. 83 Nov 143.


*(Abbreviations: Brf Consult = Brief Consultation; Puzz Case = Puzzling Case)*

Rashes and penicillin therapy. Sullivan TJ. 83 Feb 225.
Starch blockers: Is this latest fad really a food? Feldman EB. 83 Jan 303.
Treating strokes with anticoagulants. Gregoratos G. 83 Feb 300.
Ulcerative colitis. Sartor RB. 83 May 121.
Varicocele ligation. Alpern JJ, White RI. 83 Sept 133.
What are implications of hemiblock diagnosis? Kinlaw WB. 83 March 89.
What to do for chronic hiccups? Roth JLA, Greenburg JL. 83 Oct 286.
What values point to anemia in the elderly? Siegel F, Coodley E. 83 Feb 137.
Which antibiotics for a hospital pharmacy? Holloway WJ, Palmer DL. 83 Jan 241.
**Bronchitis,** chronic, diagnosis and management. Stulbarg MS. 83 Sept 167.
**Cancer,** monoclonal antibodies in management. Mitchell MS. 83 May 127.
**Carcinoid tumor,** and pheochromocytoma, how to diagnose. Feldman JH. 83 Aug 47.
and progressive heart failure. See **Clinical Case** No. 109. 83 Sept 214.
**Cardiospasm,** see **Clinical Case** No. 107. 83 July 148.
**Cardiovascular diseases,** endocarditis (Puzz Case). Pasterz R, Phibbs B. 83 July 167.
mitral stenosis causing shortness of breath (Puzz Case). Grossman J. 83 Nov 263.
risks and prognosis, women *v* men. Winternitz SR, Oparil S. 83 Feb 118.
See also specific subjects.
**Child,** abuse, facing the problem. Cohen R. 83 Dec 96.
accidental poisoning. Weston W III. 83 Sept 250.
behavior that signals underlying pain. Hahn YS. 83 Oct 219.
diffuse pneumonias of infancy. Irons TG. 83 Feb 69.
epilepsy management. Zion TE. 83 Jan 158.
essentials of neurologic examination. Trice JE, Trauner DA. 83 Nov 268.
febrile infants, assessing risks of infections. Bergman DA, Pantell RH. 83 May 49.
how to discuss death with the dying child and family. Pearson JM. 83 Sept 85.
hypertension, diagnostic pitfalls. Levine RS. 83 June 225.
infantile diarrhea, oral rehydration. Rosenberg AJ. 83 Oct 275.
investigating metabolic disease. Howell RR. 83 Nov 133.
pinpointing cause of lower GI bleeding. Kleinman MS. 83 July 77.
respiratory disorders, treatment. Cotton EK. 83 April 78.
**Clinical Cases**
No. 101. 83 Jan 248. Heart murmur in healthy 4-year-old (coarctation of the aorta). Allen HD.
No. 102. 83 Feb 252. Increasing dyspnea in previously controlled COPD (indications for oxygen therapy). Seidenfeld JJ, Tremper JC.
No. 103. 83 March 236. Recurrent deep vein thrombophlebitis—or something else? (scurvy). Connelly TJ.
No. 104. 83 April 270. Pernicious anemia in a retarded young woman—any connection? (autoimmune endocrinopathy). Ammann AJ.
No. 105. 83 May 232. Why the recurrent fever, cough, and expectoration? (Kartagener's syndrome). Sharma OP.
No. 106. 83 June 210. Baffling hypoglycemia in a 58-year-old woman (insulinoma). Cherner R.
No. 107. 83 July 148. 'His spluttering noises keep waking me up' (cardiospasm). Greenburg JL.
No. 108. 83 Aug 158. A pharmacy student with abdominal pain and anemia (Meckel's diverticulum). Selker HP.
No. 109. 83 Sept 214. Progressive heart failure (carcinoid). Kessler MR.
No. 110. 83 Oct 252. Why the rash and fever after playing ball? (SLE). Searles RP.
No. 111. 83 Nov 206. 'Doctor, I'm worried about this lump in my neck' (cancer). Strauss RD.
No. 112. 83 Dec 124. Two months of fever, anorexia, and weight loss (Wegener's granulomatosis). Sharma OP.
**Clostridial infections,** resultant toxins and syndromes. Bryan CS. 83 April 152.
**Coccidioidomycosis osteomyelitis** (Puzz Case). Amin NM, Brauer AD, Atkinson WL. 83 April 185.
**Colitis,** ulcerative, newest therapy (Brf Consult). Sartor RB. 83 May 121.
**Colostomy.** See **Ileostomy.**
**Contact lenses,** handling most common problems. Gofman JD. 83 Nov 167.
**Contraceptives, oral,** benefits and risks. Mishell DR. 83 April 139.
**COPD,** oxygen for. See **Clinical Case** No. 102. 83 Feb 252.
**Costs,** health care (editorial opinion). Murata SK. 83 Jan 330.
**Crohn's disease,** managing inflammatory bowel disease in adolescents. Hillemeier AC, McCallum RW. 83 Oct 37.
surgery and management of recurrence. Fazio VW. 83 Jan 49.
**Cystitis,** in women, errors in diagnosis and treatment. Goodall WM. 83 June 195.
**Depression,** endogenous, differential diagnosis. Talley JA. 83 Feb 105.
**Dermatitis,** the speckled accountant (Puzz Case). Dirckx JH. 83 Dec 151.
**Diabetes,** therapeutic protocols for dealing with ketoacidosis and hypoglycemia. Tyndall G, Jastremski MS. 83 Oct 57.
**Diabetes mellitus,** brittle, chronic overinsulinization. Hill LL. 83 May 31.
brittle, improved control. Geffner ME, Lippe BM. 83 Jan 175.
with coma, hypotension (Brf Consult). Whitehouse FW. 83 April 147.
diagnosis and management in elderly. Granner DK. 83 April 53.
diet therapy. Prosser PR, Anding R. 83 Dec 29.
insulinoma. See **Clinical Case** No. 106. 83 June 210.
secondary, physicians' questions (15). Field JB. 83 Feb 284.
what's new in blood glucose self-testing. Orzeck EA. 83 Aug 93.
**Diabetic neuropathies,** mechanisms of nerve injury and treatment. Parry GJ. 83 March 73.
**Diagnosis, laboratory,** understanding and using the anion gap. Hricik DE, Kassirer JP. 83 July 130.
**Diagnosis, otoscopy,** improving technique. Stool SE. 83 March 247.
**Diarrhea,** hormonally mediated (Puzz Case). Rogers A. 83 April 69.
infantile, advantages of oral rehydration. Rosenberg AJ. 83 Oct 275.
infectious, in pregnancy (Brf Consult). Ravdin JI. 83 March 145.
**Diet therapy,** for diabetes mellitus. Prosser PR, Anding R. 83 Dec 29.
**Digestive system diseases,** functional problems. Wolf S. 83 Aug 129.
**Digoxin,** See **Drug interaction.**
**Diverticulitis,** colonic perforated (Puzz Case). Abel WG. 83 Jan 325.
**Dreams** of violence (Brf Consult). Reid WH. 83 March 109.
**Drug interaction,** quinidine-digoxin (Brf Consult). Bigger JT Jr. 83 June 182.
**Drug therapy,** amitriptyline for chronic pain. Thurman BH. 83 Dec 94.
beta-blockers after MI, physicians' questions (10). Goldstein S. 83 June 93.
beta-blockers for arrhythmias. Scheidt S. 83 Feb 295.
cephalosporins, choosing the right one. Panwalker AP. 83 June 244.
in COPD. Barbee R. 83 May 139.
cyanide toxicity with nitroprusside treatment for hypertension (Puzz Case). Dunn FG. 83 Nov 201.
lidocaine during MI? (Brf Consult). Cohen SI. 83 Oct 247.
modifications with aging kidneys. Mujais SK, Gantt CL. 83 April 282.
topical steroids, use and abuse. Raimer SS, Subrt P. 83 April 243.
trimethoprim/sulfamethoxazole, physicians' questions (10). Hughes WT. 83 Oct 73.
**Drugs,** are tricyclics cardiotoxic? (Brf Consult). Patterson WM. 83 Sept 249.
**Dyspnea,** the art of diagnosis. Coodley EL. 83 Nov 281.
**Ear.** See **Diagnosis.**
**Editorial Opinion**
Mohler JG:
The high cost of breathing. 83 June 260.
Murata SK:
The year of the serpent. 83 Jan 330.
Nash DT:
Teach patients to ask 'why.' 83 Sept 262.
Stutchin AD:
Make a habit of treating addiction. 83 Oct 304.
Wassersug JD:
The little things that count. 83 Nov 312.

# NAPROSYN®
(naproxen) available in 250 mg, 375 mg, 500 mg tablets.

**Brief Summary: Contraindications:** The drug is contraindicated in patients who have had allergic reactions to NAPROSYN® (naproxen) or to ANAPROX® (naproxen sodium). Do not give to patients in whom aspirin or other nonsteroidal anti-inflammatory/analgesic drugs induce the syndrome of asthma, rhinitis, and nasal polyps. Both types of reactions have the potential of being fatal. **Warnings:** Gastrointestinal bleeding, sometimes severe, and occasionally fatal, has been reported in patients receiving the drug. Among 960 patients treated for rheumatoid arthritis or osteoarthritis, 16 cases of peptic ulceration were reported. More than half were on concomitant corticosteroid and/or salicylate therapy and about a third had a prior history of peptic ulcer. Gastrointestinal bleeding, including nine potentially serious cases, was also reported. These were not always preceded by premonitory gastrointestinal symptoms. Although most of the patients with serious bleeding were receiving concomitant therapy and had a history of peptic ulcer disease, the drug has the potential for causing gastrointestinal bleeding on its own. Administer to patients with active gastric and duodenal ulcers only under close supervision. **Precautions: General: NAPROSYN® (NAPROXEN) SHOULD NOT BE USED CONCOMITANTLY WITH THE RELATED DRUG ANAPROX® (NAPROXEN SODIUM) SINCE THEY BOTH CIRCULATE IN PLASMA AS THE NAPROXEN ANION.** Because anaphylactic reactions usually occur in patients with a history of such reactions, question patients for such things as asthma, nasal polyps, urticaria, and hypotension associated with NSAIDS before starting therapy. If such symptoms occur, discontinue the drug. In chronic studies in laboratory animals, the drug has caused nephritis. Glomerular nephritis, interstitial nephritis and nephrotic syndrome have been reported. Use with great caution in patients with significantly impaired renal function. Monitoring of serum creatinine and/or creatinine clearance is advised in these patients. Certain patients, including those with compromised renal blood flow and some elderly in whom impaired renal function may be expected, should have renal function assessed before and during therapy. Consider reducing daily dosage in these patients. With NSAIs borderline elevations of liver tests may occur in up to 15% of patients. They may progress, remain unchanged, or be transient with continued therapy. The SGPT (ALT) test is probably the most sensitive indicator of liver dysfunction. Elevations (3 times the upper limit of normal) of SGPT or SGOT (AST) occurred in controlled clinical trials in less than 1% of patients. Evaluate patients with symptoms and/or signs suggesting liver dysfunction, or in whom an abnormal liver test has occurred, for evidence of more severe hepatic reaction. Severe hepatic reactions, including jaundice and cases of fatal hepatitis, have been reported rarely. If abnormal liver tests persist or worsen, if clinical signs and symptoms consistent with liver disease develop, or if systemic manifestations occur (e.g., eosinophilia or rash), discontinue therapy. If steroid dosage is reduced or eliminated during therapy, do so slowly and observe patients closely for adverse effects, including adrenal insufficiency and exacerbation of arthritis symptoms. Determine hemoglobin values frequently for patients with initial values of 10 grams or less who receive long-term therapy. Peripheral edema has been observed in some patients. Each tablet contains approximately 25 mg (1 mEq) sodium, which should be considered in patients whose overall intake of sodium must be markedly restricted. Use with caution in patients with fluid retention, hypertension or heart failure. The antipyretic and anti-inflammatory activities of the drug may reduce fever and inflammation, thus diminishing their utility as diagnostic signs. Conduct ophthalmic studies soon after starting therapy and at periodic intervals if the drug is used for an extended period. **Information for Patients:** Caution should be exercised by patients whose activities require alertness if they experience drowsiness, dizziness, vertigo or depression during therapy. **Drug Interactions:** Naproxen anion may displace other albumin-bound drugs from their binding sites and could likewise be displaced itself. Studies failed to show that the drug significantly affects prothrombin times when administered to individuals on coumarin-type anticoagulants, but use caution since interactions have been seen with other nonsteroidal agents of this class. Observe patients receiving the drug and a hydantoin, sulfonamide or sulfonylurea for signs of toxicity to these drugs. Some drugs of this class inhibit the natriuretic effect of furosemide. Increased plasma lithium due to inhibition of renal lithium clearance has been reported. This drug and other NSAIs can reduce the antihypertensive effect of beta-blockers. Probenecid given concurrently increases naproxen anion plasma levels and extends its plasma half-life significantly. **Drug/Laboratory Test Interactions:** The drug may decrease platelet aggregation and prolong bleeding time. The drug may result in increased urinary values for 17-ketogenic steroids because of an interaction between the drug and/or its metabolites with m-dinitrobenzene used in this assay. Temporarily discontinue therapy with the drug for 72 hours before adrenal function tests are performed. The drug may interfere with some urinary assays of 5-hydroxy indoleacetic acid (5HIAA). **Carcinogenesis:** A two-year study in rats to evaluate the carcinogenic potential of the drug showed no evidence of carcinogenicity. **Pregnancy:** Teratogenic Effects: Pregnancy Category B. Do not use during pregnancy unless clearly needed. Avoid use during late pregnancy. Non-teratogenic Effects: In rats, pregnancy was prolonged when the drug was given before the onset of labor; labor was protracted when the drug was given after labor had begun. **Nursing Mothers:** Avoid use in nursing mothers. **Pediatric Use:** Pediatric indications and dosage recommendations have not been established. **Adverse Reactions: Incidence Greater Than 1%: Gastrointestinal:** The most frequent complaints related to the gastrointestinal tract: constipation,* heartburn,* abdominal pain,* nausea,* dyspepsia, diarrhea, stomatitis. **Central Nervous System:** Headache,* dizziness,* drowsiness,* lightheadedness, vertigo. **Dermatologic:** Itching (pruritus),* skin eruptions,* ecchymoses,* sweating, purpura. **Special Senses:** Tinnitus,* hearing disturbances, visual disturbances. **Cardiovascular:** Edema,* dyspnea,* palpitations. **General:** Thirst. *Incidence of reported reaction 3%-9%. Reactions seen in less than 3% of the patients are unmarked. **Incidence Less Than 1%: Probable Causal Relationship:** The following adverse reactions were reported less frequently than 1% during controlled clinical trials and through voluntary reports since marketing. The probability of a causal relationship exists between the drug and these adverse reactions: Abnormal liver function tests, gastrointestinal bleeding, hematemesis, jaundice, melena, peptic ulceration with bleeding and/or perforation, vomiting, glomerular nephritis, hematuria, interstitial nephritis, nephrotic syndrome, renal disease, eosinophilia, granulocytopenia, leukopenia, thrombocytopenia, depression, dream abnormalities, inability to concentrate, insomnia, malaise, myalgia and muscle weakness, alopecia, skin rashes, hearing impairment, congestive heart failure, anaphylactoid reactions, menstrual disorders, pyrexia (chills and fever). **Causal Relationship Unknown:** Other reactions have been reported in circumstances in which a causal relationship could not be established. However, in these rarely reported events, the possibility cannot be excluded. Therefore these observations are being listed to serve as alerting information to the physicians: agranulocytosis, aplastic anemia, hemolytic anemia, urticaria, angioneurotic edema, hyperglycemia, hypoglycemia. **Overdosage:** May be characterized by drowsiness, heartburn, indigestion, nausea or vomiting. Life-threatening dose is not known. If patient ingests many tablets, empty stomach and employ usual supportive measures. Animal studies suggest that the prompt administration of 5 grams of activated charcoal would tend to reduce markedly drug absorption. It is not known if the drug is dialyzable. **Caution:** Federal law prohibits dispensing without prescription. See package insert for full prescribing information.
August 1983 Rev. 24

SYNTEX Syntex Puerto Rico, Inc.
Humacao, P.R. 00661



**Endocrinopathy,** autoimmune. See **Clinical Case** No. 104. 83 April 270.
**Epilepsy,** managing childhood onset. Zion TE. 83 Jan 158.
**Esophageal varices,** problems of selecting therapy. Smith JL, Graham DY. 83 Oct 86.
**Exercise therapy,** patient evaluation for aerobic program. Taylor RB. 83 April 94.
**Eye diseases,** retinopathy associated with hypertension. Walsh JB. 83 Sept 113.
**Eye injuries,** 'black eye,' corneal abrasions, other trauma. Cyrlin MN. 83 Jan 109.
prevention of sports-related trauma. Holt JE. 83 July 117.
**Fibrocystic disease,** breast, new therapy. Vaughn TC. 83 June 129.
**Gastric mucosa prolapse,** differential diagnosis and treatment. Lichstein J. 83 Sept 57.
**Gastrointestinal diseases.** See specific subjects.
**Geriatrics.** See **Aged.**
**Gonorrhea,** management. Bryan CS. 83 Feb 83.
**Gynecology,** office tests. Abrams J. 83 Sept 179.
**Head injuries,** roadside coma (Puzz Case). Raskind R. 83 July 211.
**Hearing disorders,** impaired hearing in the elderly. Katz AE. 83 May 59.
**Hearing loss,** noise-induced, evaluating occupational problems. Conibear SA. 83 July 45.
**Heart auscultation,** murmurs in the elderly. Ewy GA. 83 March 151.
**Heart diseases,** beta-blockers after MI, physicians' questions (10). Goldstein S. 83 June 93.
beta-blockers for arrhythmias. Scheidt S. 83 Feb 295.
diagnosis with chest x-ray studies. Wolk PJ, Cheitlin MD. 83 Jan 195.
drugs and techniques for myocardial preservation. Shea MJ, Lucchesi BR. 83 Feb 175.
mitral stenosis (Puzz Case). Grossman J. 83 Nov 263.
pacemakers for tachycardia. Das Gupta DS. 83 May 199.
postcoronary sexual problems. Papadopoulos C. 83 April 303.
risk factors for CHD. Borhani NO. 83 May 77.
role of HDL in preventing. Kreisberg RA. 83 Oct 197.
sudden coronary death, prevention. Dalen JE, Goldberg RJ. 83 April 219.
use of angiocardiography post MI. Marpole DGF. 83 March 224.
See also specific subjects.
**Hemangiomas,** cutaneous, which ones to treat. Chapman J, Rosen T. 83 Oct 289.
**Hemiblock,** meaning of (Brf Consult). Kinlaw WB. 83 March 89.
**Hemorrhage, gastrointestinal,** pinpointing cause in children and young adults. Kleinman MS. 83 July 77.
**Hepatitis, viral,** serologic markers and immune response. Blum HEC, Vyas GN. 83 Sept 195.
**Herpes zoster,** managing recurrent

episodes. Griffin DE. 83 Oct 231.
**Hiccup,** chronic, what to do for (Brf Consult). Roth JLA, Greenburg JL. 83 Oct 286.
**Homeopathy,** a historic review (Brf Consult). Barrett S. 83 Oct 173.
**Homosexuality,** in adolescence, 10 don'ts for parents. Mead BT. 83 April 107.
**Hyperparathyroidism,** primary (Puzz Case). Lueg MC. 83 May 149.
**Hyperphosphatemia** with normal kidney function (Brf Consult). Manning RT. 83 Feb 269.
**Hypersplenism,** when to treat. Crosby WH. 83 June 103.
**Hypertension,** associated retinopathy. Walsh JB. 83 Sept 113.
and calcium, clinical implications. Grady JR, McCarron DA. 83 Aug 212.
childhood, diagnostic pitfalls. Levine RS. 83 June 225.
with concomitant renal disease. Mailloux LU. 83 Nov 97.
patient compliance. Sackett DL, Haynes RB, Taylor DW. 83 Jan 287.
practical work-up for new patients. Mackowiak R. 83 March 80.
is stepped care really desirable? Pickering TG. 83 Oct 105.
**Hypocalcemia,** clinical manifestations. Rastogi SP, Arruda JAL. 83 July 92.
**Hypoglycemia,** therapeutic protocols. Tyndall G, Jastremski MS. 83 Oct 57.
the true disorder and the myth. Olson OC. 83 Nov 35.
**Ichthyosis,** diagnosis and management. Epstein EH Jr. 83 Feb 233.
**Ileostomy,** and sexual adjustment. Renshaw DC. 83 March 113.
stoma management. Gouge TH, Purcell EA, Localio SA. 83 Feb 45.
**Immunologic deficiency syndromes,** the facts about AIDS. Ammann AJ. 83 Sept 35.
**Infection,** intra-abdominal, radiographic diagnosis. Broderick TW. 83 Jan 257.
physicians' questions about superinfection. Sen P, Louria DB. 83 Nov 302.
serodiagnosis of bacterial and rickettsial organisms. Drew WL. 83 Feb 140.
serodiagnosis of viral, fungal, parasitic organisms. Drew WL. 83 March 123.
skin, atypical mycobacteria. Owens DW. 83 March 252.
See also specific subjects.
**Influenza vaccine,** recommendations for 1983-84. Douglas RG Jr. 83 Oct 31.
**Insomnia,** due to anesthetic? (Brf Consult). Maxmen JS, Carron H. 83 June 45.
**Islet-cell tumor** (Puzz Case). Lueg MC. 83 June 114.
**Jaundice, neonatal,** exchange transfusion, phototherapy, or observation? Cashore WJ, Oh W. 83 Dec 51.
**Joint diseases,** sacroiliitis, those persons at risk. Ryan LM. 83 Jan 127.
**Kartagener's syndrome.** See **Clinical Case** No. 105. 83 May 232.
**Kidney,** drug metabolism in old age. Mujais SK, Gantt CL. 83 April 282.
**Kidney failure, acute,** diagnosis in adolescence. McCrory WW. 83 March 167.
**Labyrinthian disorder,** cause of (Brf Consult). Raskind R, Smith RW. 83 March 181.
**Lipids, serum,** measurement and interpretation. Cohen KL. 83 Dec 76.
**Lipoproteins,** HDL, a delicate balance helps prevent CHD. Kreisberg RA. 83 Oct 197.
**Liver diseases,** acute hepatic failure. Koff RS. 83 May 248.
using breath tests to diagnose. King CE, Toskes PP. 83 Nov 117.
**Lung,** hydrocarbon ingestion, smoke inhalation, near-drowning. Hopkins RL. 83 July 33.
**Lung diseases,** chronic bronchitis. Stulbarg MS. 83 Sept 167.
COPD, choice of drug therapy. Barbee R. 83 May 139.
diffuse interstitial pulmonary fibrosis (Puzz Case). Lending RE. 83 March 63.
**Lung neoplasms,** and headache (Brf Consult). Marsh JC. 83 Nov 143.
**Lupus erythematosus, systemic.** See **Clinical Case** No. 110. 83 Oct 252.
**Meckel's diverticulum.** See **Clinical Case** No. 108. 83 Aug 158.
**Menstruation disorders,** anovulation and dysfunctional uterine bleeding. Charpentier LA. 83 Feb 274.
**Metabolic diseases,** asymptomatic hyperuricemia, physicians' questions (8). Arnold WJ. 83 Jan 37.
in children. Howell RR. 83 Nov 133.
**Migraine,** symptoms other than headache. Kunkel RS. 83 April 231.
**Mouth diseases,** chronic erosive blisters. Bean SF. 83 April 295.
**Multiple myeloma,** IVP complication in patient with (Puzz Case). Grossman J. 83 June 202.
**Multiple sclerosis,** mystery of impaired gait (Puzz Case). Giesser B, Scheinberg L. 83 Jan 153.
**Muscular diseases,** evaluating rhabdomyolysis. Bethune JE. 83 Sept 137.
**Myocardial infarction,** and lifestyle changes. Wenger NK. 83 Aug 111.
**Neoplasms,** of the bladder. Paulson DF. 83 Sept 151.
esophageal. Kelsen DP. 83 Nov 247.
head and neck. See **Clinical Case** No. 111. 83 Nov 206.
of the lung, and headache (Brf Consult). Marsh JC. 83 Nov 143.
stomach, improving survival. Douglass HO. 83 Oct 177.
of the thyroid. Sarne DH, DeGroot LJ. 83 Sept 232.
treating pain as disease. Ferrer-Brechner T. 83 April 35.
**Nephrotic syndrome** (Puzz Case). Pasterz R, Phibbs B. 83 Oct 240.
**Neurologic examination,** in children. Trice JE, Trauner DA. 83 Nov 268.
**Nevus,** when significance is more than skin deep. Alper JC, Holmes LB. 83 March 41.
**Nutrition,** dietary adjustments during pregnancy. Udall JN. 83 July 170.
general recommendations. Nestle M. 83 Jan 271.
**Obesity,** behavioral strategies for losing weight. Foreyt JP, Gotto AM Jr. 83 March 200.
starch blockers, fad or food? (Brf Consult). Feldman EB. 83 Jan 303.
**Occupational diseases,** noise-induced hearing loss. Conibear SA. 83 July 45.
poisoning in the workplace. Levy BS. 83 Nov 63.
**Oxygen,** use in COPD. See **Clinical Case** No. 102. 83 Feb 252.
**Pacemaker, artificial,** tachycardia management. Das Gupta DS. 83 May 199.
**Pain,** associated behavior in children. Hahn YS. 83 Oct 219.
chronic, amitriptyline therapy for (Brf Consult). Thurman BH. 83 Dec 94.
chronic, therapeutic strategies. Carron H. 83 Dec 59.
management in cancer. Ferrer-Brechner T. 83 April 35.
**Parasitic diseases,** amebiasis and giardiasis. Weller PF. 83 April 115.
therapy for ascariasis infections. Beutel WD, Allison JG. 83 July 213.
**Patient compliance,** hypertension therapy. Sackett DL, Haynes RB, Taylor DW. 83 Jan 287.
**Pediatrics.** See **Child.**
**Peptic ulcer,** recurrent, physicians' questions (10). Fleshler B. 83 March 33.
**Pheochromocytoma,** and malignancy, how to diagnose. Feldman JH. 83 Aug 47.
**Photoclinic**
83 Jan 233. Scarlet fever, pseudohypertrophic muscular dystrophy, mucosal neuromas, familial medullary carcinoma of thyroid, flat warts, cutaneous larva migrans, gigantism.
83 Feb 217. Oral mucocele, caudal regression syndrome, basal cell carcinoma, porphyria cutanea tarda, striae, noninflammatory tinea capitis.
83 March 217. Squamous cell carcinoma, EMG syndrome, lamellar ichthyosis, Bowen's disease, secondary syphilis.
83 April 225. Primary herpes simplex, serum sickness, sterile abscess, erythema infectiosum, basal cell carcinoma.
83 May 179. Erysipelas, pretibial myxedema, bilateral dacryostenosis, pemphigus erythematosus, trichophytic granuloma, thrombocytopenia with absent radii syndrome.
83 June 185. Lead poisoning, sarcoidosis, rabies prophylaxis, pityriasis rubra pilaris, necrobiosis lipoidica diabeticorum.
83 July 183. Papilledema, tinea versicolor, alopecia, toxic epidermal necrolysis (TEN), Bowenoid papulosis, seborrheic dermatitis.
83 Aug 123. Mucocele, rheumatoid arthritis, tuberous sclerosis, Rendu-Osler-Weber disease.
83 Sept 187. Wilson's disease, bullous impetigo, trichotillomania, septic emboli, lymphogranuloma venereum, nickel contact dermatitis, lichen sclerosus et atrophicus.

83 Oct 213. Dermatomyositis, pseudomonas infection, epidemic keratoconjunctivitis, mycoplasmal pneumonia.
83 Nov 177. Scabies, Graves' disease, superficial basal cell carcinoma, miliary tuberculosis, secondary syphilis.
83 Dec 117. Kaposi's sarcoma, pancreatic calcification, actinic keratoses, infectious eczematoid dermatitis, leukocytoclastic vasculitis, scarlet fever.
**Physical fitness,** prescribing exercises for patients. Payne FE Jr. 83 Aug 188.
**Pneumonia,** best diagnostic options for difficult cases. Bone RC. 83 Oct 113.
diffuse, in infants. Irons TG. 83 Feb 69.
managing *Pneumocystis carinii* infections. Amin NM. 83 Jan 71.
**Poisoning,** aspirin and acetaminophen overdose. Teitelbaum DT, Teitelbaum SB. 83 Feb 195.
chemical exposure in the workplace. Levy BS. 83 Nov 63.
in children. Weston W III. 83 Sept 250.
**Practical Pointers** (see also **Tips**).
Advancing an I.V. with ease. 83 July 127.
Arthritis therapy, warming paraffin. 83 Jan 222.
Auscultating the heart. 83 June 112.
Auscultation of lungs. 83 Jan 300.
Bacterial pneumonia masquerading as flu relapse. 83 Feb 230.
Bad breath a clue to bezoars. 83 Nov 301.
Beclomethasone dipropionate remedy for nose spray abuse. 83 May 231.
Of biting concern. 83 Dec 93.
Buffy coat smear technique. 83 Feb 264.
Caution on anti-inflammatories. 83 Oct 272.
Clearing confusion from valves and cusps. 83 Nov 301.
Defogging laryngeal mirror. 83 Feb 230.
Differentiating abdominal visceral trauma from rectus muscle trauma. 83 April 304.
Earache from erupting wisdom tooth. 83 Jan 300.
Easier ion exchange enemas. 83 Aug 172.
Easy tube gauze application. 83 June 112.
English to metric conversion. 83 Dec 168.
Eye examination without anesthesia. 83 July 127.
'Handy' balloon. 83 Sept 146.
Have ECG, will travel. 83 Aug 172.
Hiccups, treatment with white corn syrup. 83 Feb 230.
I.M. injection and needle length. 83 Oct 272.
Initial it. 83 Dec 93.
Inserting CVP line. 83 Feb 264.
Interpreting pulse-temperature deficit. 83 April 304.
Maintaining walking casts. 83 May 231.
Making a colostomy bag fit. 83 July 192.
Making pediatric otoscopic examinations easier. 83 Aug 172.
Measuring pupil accommodation in blacks. 83 May 231.
Mnemonic for pulmonary edema. 83 Dec 93.
Passing nasogastric tube in comatose patient. 83 April 304.
Pinch in, blow out. 83 Dec 168.
Pre-vasectomy semen analysis. 83 Jan 222.
Preventing pneumothorax. 83 July 192.
Puncture-wound probe. 83 Nov 301.
Reducing laryngeal mirror fog. 83 June 112.
Removing insects from the ear with ether. 83 July 192.
Removing pill fragments. 83 Sept 146.
Sounding out an artery. 83 Sept 146.
Spotting herpes blisters. 83 Dec 168.
Summarizing patient record at discharge. 83 Feb 264.
Tape the hair. 83 Dec 93.
Technique for distracting pediatric patients. 83 Jan 300.
Testing reflexes. 83 June 112.
Travel directions for patients. 83 Jan 222.
X-ray vision aid. 83 Sept 146.
**Pregnancy,** complications in adolescence. Green KW. 83 May 187.
the dangers of drug use. Erbe RW. 83 Nov 185.
dietary adjustments for mother and fetus. Udall JN. 83 July 170.
premature labor, intervention. Brinkman CR III. 83 Jan 223.
**Prostatic neoplasms,** diagnosis and therapy. Geller J, Albert JD. 83 Feb 29.
**Pruritus ani,** therapeutic strategy. Webster SB. 83 Jan 311.
**Pulmonary diseases.** See **Lung diseases.**
**Pulmonary edema,** caused by drugs or oxygen? (Brf Consult). Wolinsky H. 83 July 147.
**Puzzling Cases**
Bleeding and timely tests. Lerner RG. 83 Oct 136.
The case of the tired young man. Pasterz R, Phibbs B. 83 Oct 240.
Continual diarrhea of 10 days' duration (hormonally mediated diarrhea). Rogers A. 83 April 69.
Finger lesion that would not heal (coccidioidomycotic osteomyelitis). Amin NM, Brauer AD, Atkinson WL. 83 April 185.
Mystery of impaired gait (multiple sclerosis). Giesser B, Scheinberg L. 83 Jan 153.
Roadside coma. Raskind R. 83 July 211.
Seesaw of abdominal pain (perforated diverticulum). Abel WG. 83 Jan 325.
Short of breath day and night (mitral stenosis). Grossman J. 83 Nov 263.
The speckled accountant (fir-tree irritation). Dirckx JH. 83 Dec 151.
Tomato juice and renal failure (IVP complication in patient with multiple myeloma). Grossman J. 83 June 202.
Unremitting fever (diffuse interstitial pulmonary fibrosis). Lending RE. 83 March 63.
Was it just pneumonia? Pasterz R, Phibbs B. 83 July 167.
What was wrong with the 'bag lady?' (primary hyperparathyroidism). Lueg MC. 83 May 149.
Why the high cyanide levels? (nitroprusside therapy). Dunn FG. 83 Nov 201.
Why the seizure after playing ball? (islet-cell adenoma). Lueg MC. 83 June 114.
**Questions physicians often ask . . .**
asymptomatic hyperuricemia (8). Arnold WJ. 83 Jan 37.
beta-blockers after MI (10). Goldstein S. 83 June 93.
recurrent peptic ulcer (10). Fleshler B. 83 March 33.
secondary diabetes (15). Field JB. 83 Feb 284.
**Quinidine,** see **Drug interaction.**
**Rabies,** when to immunize. Brunell PA. 83 May 258.
**Radiography,** diagnosis of intra-abdominal infections. Broderick TW. 83 Jan 257.
**Respiratory tract diseases,** treating childhood disorders. Cotton EK. 83 April 78.
**Respiratory tract infections,** diagnosing laryngitis and tracheitis. Grossman TW. 83 Aug 63.
**Scurvy** and thrombophlebitis. See **Clinical Case** No. 103. 83 March 236.
**Serodiagnosis,** bacterial, rickettsial infections. Drew WL. 83 Feb 140.
viral, fungal, and parasitic infections. Drew WL. 83 March 123.
**Sex,** adjusting to an ostomy. Renshaw DC. 83 March 113.
after heart attack. Papadopoulos C. 83 April 303.
**Shoulder, pain,** diagnostic manipulation. Weiker GG. 83 Dec 38.
**Skin,** hemangiomas, which ones to treat. Chapman J, Rosen T. 83 Oct 289.
**Skin diseases,** atypical mycobacterial infections. Owens DW. 83 March 252.
use and abuse of topical steroids. Raimer SS, Subrt P. 83 April 243.
**Skin tests,** patch testing for allergens. Maibach HI. 83 April 201.
**Sleep,** gauging the need for it (Brf Consult). Carskadon MA, Dement WC. 83 Nov 296.
**Sleep disorders,** daytime hypersomnia, clinical significance. Dement WC, Carskadon MA. 83 March 182.
'hidden' cause of cardiopulmonary disorders. Guilleminault C, Mondini S. 83 July 193.
**Spinal cord injuries,** early evaluation and management. Goodkin R. 83 May 211.
**Sports medicine,** stress and amateur athletes. Garfinkel D. 83 Jan 136.
**Stomach neoplasms,** how we can improve survival. Douglass HO. 83 Oct 177.
**Stress,** and amateur athletics. Garfinkel D. 83 Jan 136.
**Stroke,** anticoagulant therapy (Brf Consult). Gregoratos G. 83 Feb 300.
cerebral, in young man (Brf Consult). Sherman DE. 83 April 265.
**Suicide,** prevention. Talley JH. 83 June 33.
**Thrombophlebitis** and scurvy. See **Clinical Case** No. 103. 83 March 236.
**Thyroid neoplasms,** look for a history of irradiation. Sarne DH, DeGroot LJ. 83 Sept 232.

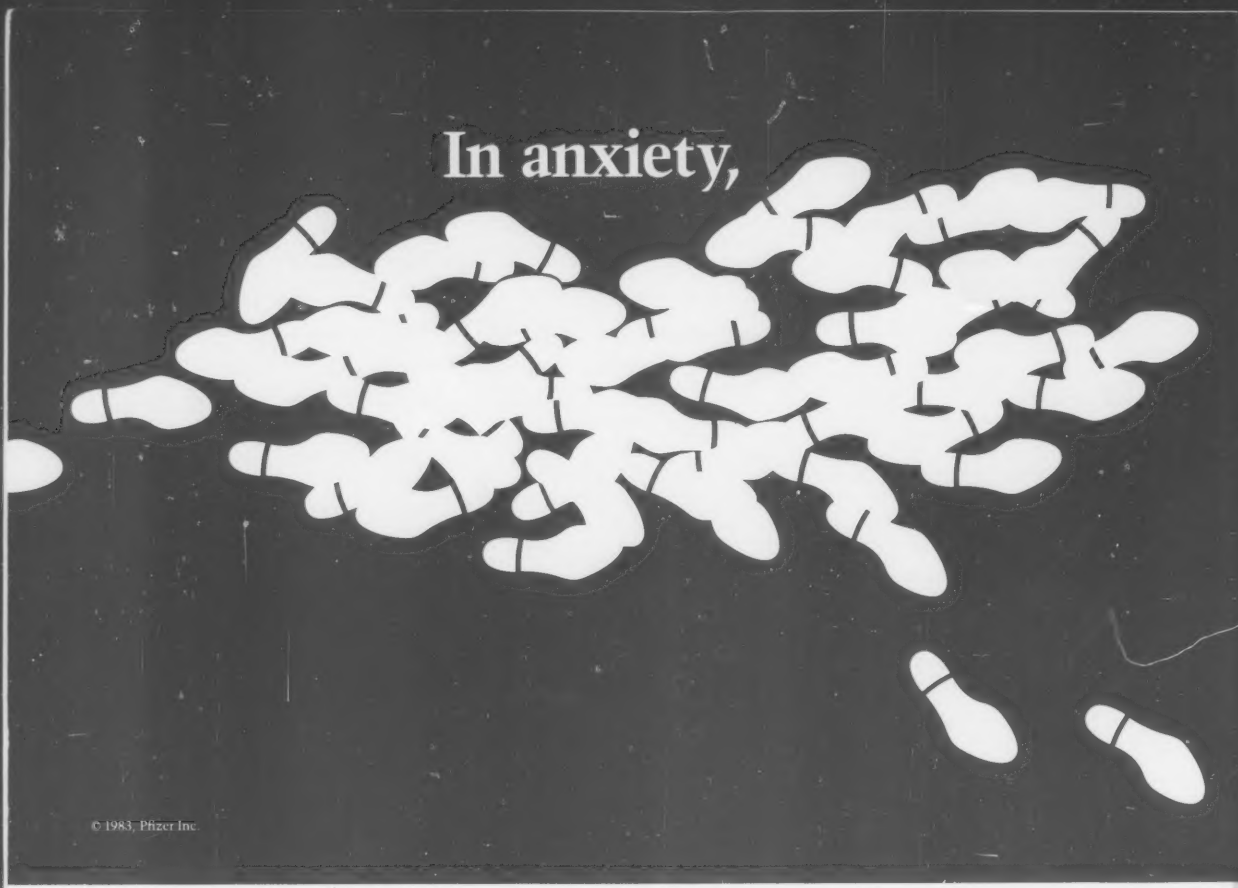
## YEAR-END INDEX


**Tips** (see also **Practical Pointers**).
Checking newborn's eyes. 83 May 253.
Cold comfort. 83 Sept 182.
Drug side effects, mislabeled container. 83 March 75.
Easier-to-find sutures. 83 Nov 306.
Easy measurement of tuberculin induration. 83 April 212.
Elevated calcium due to drug therapy. 83 Jan 144.
Esophageal reflux a cause of nocturnal asthma. 83 April 258.
Fixing a foreign body. 83 Nov 74.
$H_2O_2$ clears the canal. 83 Aug 117.
Irrigating contaminated wounds. 83 April 284.
Keeping track of drug usage. 83 May 189.
Meperidine for myoclonic activity due to severe infection. 83 April 179.
Nondrug therapy for anxiety. 83 May 81.
Peruvian balsam and some steroids don't mix. 83 Dec 71.
Pinpointing catheter tip. 83 July 121.
Possible cause of hyponatremia. 83 Nov 104.
Pressure reveals veins. 83 Dec 84.
Sanitation standards of cruise ships. 83 June 36.
Splinting a nose break. 83 Nov 191.
Surmounting high-altitude sickness with acetazolamide. 83 Jan 225.
TRH thyroid test. 83 March 34.
Uses for needle in soft tissue wounds. 83 April 222.
Using nasal decongestants. 83 Jan 307.
**Ulcerative colitis**, managing inflammatory bowel disease in adolescents. Hillemeier AC, McCallum RW. 83 Oct 37.
**Uric acid.** See **Metabolic diseases** and **Questions physicians often ask . . .**
**Vaccination**, influenza vaccine, recommendations for 1983-84. Douglas RG Jr. 83 Oct 31.
**Varicocele**, ligation (Brf Consult). Alpern JJ, White RI. 83 Sept 133.
**Varicose veins**, treatment and prevention. Baron HC. 83 May 108.
**Violence**, short-circuiting abusive behavior in the family. Arnold JF. 83 July 204.
**Vitamin K deficiency** (Puzz Case). Lerner RG. 83 Oct 136.
**Wegener's granulomatosis.** See **Clinical Case** No. 112. 83 Dec 124.


## INDEX TO AUTHORS


**Abel, William G** diverticulum, perforated (Puzz Case), 83 Jan 325.
**Aberman, Arnold** asthma diagnosis and treatment, 83 June 143.
**Abrams, Jerome** office gynecology procedures, 83 Sept 179.
**Albert, Jerry D** prostate cancer, 83 Feb 29.
**Allen, Hugh D** aortic coarctation (Clinical Case No. 101), 83 Jan 248.
**Allison, John G** ascariasis, 83 July 213.
**Alper, Joseph C** birthmarks, 83 March 41.
**Alpern, Joshua J** varicocele ligation (Brf Consult), 83 Sept 133.
**Ames, Frederick C** biopsy of breast lesions, 83 March 95; breast neoplasm (Brf Consult), 83 July 65.
**Amin, Navinchandra M** coccidioidomycotic osteomyelitis (Puzz Case), 83 April 185; *pneumocystis carinii*, 83 Jan 71.
**Ammann, Arthur J** autoimmune endocrinopathy (Clinical Case No. 104), 83 April 270; the facts about AIDS, 83 Sept 35.
**Anderson, Richard E** autopsy, 83 April 256.
**Anderson, Richard O** anxiety attacks, 83 Aug 177.
**Anding, Roberta** diet therapy for diabetes mellitus, 83 Dec 29.
**Arnold, Jeanne F** abusive behavior in the family, 83 July 204.
**Arnold, William J** asymptomatic hyperuricemia, 83 Jan 37.
**Arruda, José AL** hypocalcemia, 83 July 92.
**Atkinson, William L** coccidioidomycotic osteomyelitis (Puzz Case), 83 April 185.
**Barbee, Robert** drugs in COPD, 83 May 139.
**Baron, Howard C** varicose veins. 83 May 108.
**Barrett, Stephen** a historic look at homeopathy (Brf Consult), 83 Oct 173.
**Bean, Samuel F** mouth blisters, 83 April 295.
**Bergman, David A** febrile infants, 83 May 49.
**Bethune, John E** evaluating rhabdomyolysis, 83 Sept 137.
**Beutel, William D** ascariasis, 83 July 213.
**Bigger, J Thomas Jr** quinidine-digoxin interaction (Brf Consult), 83 June 182.
**Bisel, Harry F** breast neoplasm, 83 July 65.
**Blum, Hubert EC** viral hepatitis, 83 Sept 195.
**Bone, Roger C** evaluation of difficult pneumonias, 83 Oct 113.
**Borhani, Nemat O** CHD risk factors, 83 May 77.
**Bortz, Walter M II** activity for elderly, 83 Jan 304.
**Brauer, Albert D** coccidioidomycotic osteomyelitis (Puzz Case), 83 April 185.
**Brinkman, Charles R III** premature labor, 83 Jan 223.
**Broderick, Thomas W** radiographic diagnosis of abdominal infections, 83 Jan 257.
**Brown, Elmer B** anemia of chronic disease, 83 Nov 235.
**Brunell, Philip A** rabies, 83 May 258.
**Bryan, Charles S** clostridial infections, 83 April 152; gonorrhea, 83 Feb 83.
**Cardoni, Alex A** bites and stings from marine animals, 83 Aug 29.
**Carron, Harold** chronic pain, 83 Dec 59; insomnia due to anesthetic? (Brf Consult), 83 June 45.
**Carskadon, Mary A** daytime hypersomnia, 83 March 182; gauging the need for sleep (Brf Consult), 83 Nov 296.
**Cashore, William J** neonatal jaundice, 83 Dec 51.
**Chapman, Julie** cutaneous hemangiomas, 83 Oct 289.
**Charpentier, Leonard A** dysfunctional uterine bleeding, 83 Feb 274.
**Cheitlin, Melvin D** x-ray diagnosis of heart diseases, 83 Jan 195.
**Cherner, Rachmel** insulinoma (Clinical Case No. 106), 83 June 210.
**Cohen, Kenneth L** measurement of serum lipids, 83 Dec 76.
**Cohen, Ruth** child abuse, 83 Dec 96.
**Cohen, Stafford I** lidocaine during MI? (Brf Consult), 83 Oct 247.
**Conibear, Shirley A** noise-induced hearing loss, 83 July 45.

**Connelly, Thomas J** scurvy (Clinical Case No. 103), 83 March 236.
**Coodley, Eugene L** anemia, lab values in elderly (Brf Consult), 83 Feb 137; the art of investigating dyspnea, 83 Nov 281.
**Correia, Carol J** bites and stings from marine animals, 83 Aug 29.
**Cotton, Ernest K** pediatric respiratory disorders, 83 April 78.
**Cowan, Michael N** contraindications to air travel, 83 April 177.
**Crosby, William H** hypersplenism, 83 June 103.
**Cyrlin, Marshall N** eye injuries, 83 Jan 109.
**Dalen, James E** preventing sudden coronary death, 83 April 219.
**Das Gupta, DS** pacemakers for tachycardia, 83 May 199.
**DeGroot, Leslie J** thyroid neoplasms, 83 Sept 232.
**Dement, William C** daytime hypersomnia, 83 March 182; gauging the need for sleep (Brf Consult), 83 Nov 296.
**DeShazo, Richard D** JRA diagnosis, 83 May 93.
**Dirckx, John H** the speckled accountant (Puzz Case), 83 Dec 151.
**Douglas, R Gordon** flu vaccine recommendations for 1983-84, 83 Oct 31.
**Douglass, Harold O** improving survival in gastric cancer, 83 Oct 177.
**Drew, W Lawrence** serodiagnosis of bacterial and rickettsial organisms, 83 Feb 140; serodiagnosis of viral, fungal, parasitic organisms, 83 March 123.
**Dunn, Francis G** cyanide toxicity with nitroprusside therapy (Puzz Case), 83 Nov 201.
**Epstein, Ervin H Jr** ichthyosis, 83 Feb 233.
**Erbe, Richard W** drugs and pregnancy, 83 Nov 185.
**Ewy, Gordon A** heart murmurs in elderly, 83 March 151.
**Fazio, Victor W** Crohn's disease, 83 Jan 49.
**Feldman, Elaine B** starch blockers, food or fad? (Brf Consult), 83 Jan 303.
**Feldman, Jerome H** pheochromocytoma and carcinoid, 83 Aug 47.
**Ferrer-Brechner, Theresa** pain as disease, 83 April 35.
**Field, James B** secondary diabetes (physicians' questions), 83 Feb 284.
**Fleshler, Bertram** peptic ulcer (physicians' questions), 83 March 33.
**Foreyt, John P** obesity, 83 March 200.
**Gantt, Clarence L** drug therapy with aging kidneys, 83 April 282.
**Garfinkel, Daniel** amateur sports and stress, 83 Jan 136.
**Geffner, Mitchell E** brittle diabetes, 83 Jan 175.
**Geller, Jack** prostate cancer, 83 Feb 29.
**Giesser, B** multiple sclerosis (Puzz Case), 83 Jan 153.
**Ginsburg, Robert** variant angina, 83 June 166.
**Gofman, John D** contact lens problems, 83 Nov 167.
**Goldberg, Robert J** preventing sudden coronary death, 83 April 219.
**Goldstein, Sidney** beta-blockers after MI (physicians' questions), 83 June 93.
**Goodall, William M** cystitis in women, 83 June 195.
**Goodkin, Robert** spinal cord injuries, 83 May 211.
**Gotto, Antonio M Jr** obesity, 83 March 200.
**Gouge, Thomas H** stoma management, 83 Feb 45.
**Grady, James R** hypertension and calcium, 83 Aug 212.
**Graham, David Y** therapy for variceal hemorrhage, 83 Oct 86.
**Granner, Daryl K** diabetes diagnosis and management, 83 April 53.
**Green, Karen W** teenage pregnancy complications, 83 May 187.
**Greenburg, Jerry L** cardiospasm (Clinical Case No. 107), 83 July 148; chronic hiccups (Brf Consult), 83 Oct 286.
**Gregoratos, Gabriel** anticoagulant therapy for stroke (Brf Consult), 83 Feb 300.
**Griffin, Diane E** managing shingles, 83 Oct 231.
**Grossman, Joshua** IVP complication in patient with multiple myeloma (Puzz Case), 83 June 202; mitral valve disease (Puzz Case), 83 Nov 263.
**Grossman, Thomas W** diagnosing laryngitis and tracheitis, 83 Aug 63.
**Guilleminault, Christian** sleep disorders and arrhythmias, 83 July 193.
**Hahn, Yoon S** pain behavior in children, 83 Oct 219.
**Haynes, R Brian** patient compliance in hypertension, 83 Jan 287.
**Headington, John T** alopecia, 83 Aug 137.
**Hill, L Leighton** brittle diabetes, overinsulinization, 83 May 31.
**Hillemeier, A Craig** inflammatory bowel disease in adolescents, 83 Oct 37.
**Holloway, William J** antibiotics, which ones to stock in a hospital pharmacy? (Brf Consult), 83 Jan 241.
**Holmes, Lewis B** birthmarks, 83 March 41.
**Holt, Jean E** sports-related eye trauma, 83 July 117.
**Hopkins, Robert L** pulmonary emergencies, 83 July 33.
**Howell, John BL** psychogenic breathlessness, 83 Nov 151.
**Howell, R Rodney** metabolic disease in children, 83 Nov 133.
**Hricik, Donald E** using the anion gap, 83 July 130.
**Hughes, Walter T** trimethoprim/sulfamethoxazole (physicians' questions), 83 Oct 73.
**Irons, Thomas G** pneumonias of infancy, 83 Feb 69.
**Jastremski, Michael S** ketoacidosis and hypoglycemia, 83 Oct 57.
**Jay, Stephen** isoniazid therapy (Brf Consult), 83 Aug 209.
**Kandel, Gabor** asthma diagnosis and treatment, 83 June 143.
**Kassirer, Jerome P** using the anion gap, 83 July 130.
**Katz, Arnold E** hearing loss in elderly, 83 May 59.
**Kelsen, David P** esophageal carcinoma, 83 Nov 247.
**Kessler, Michael R** carcinoid and heart failure (Clinical Case No. 109), 83 Sept 214.
**King, Charles E** breath testing in GI and liver disorders, 83 Nov 117.
**Kinlaw, W Bernard** implications of hemiblock (Brf Consult), 83 March 89.
**Kleinman, Martin S** lower GI bleeding in children, 83 July 77.
**Koff, Raymond S** acute liver failure, 83 May 248.
**Kreisberg, Robert A** HDL in prevention of CHD, 83 Oct 197.
**Kulund, Daniel N** cycling injuries, 83 June 83.
**Kunkel, Robert S** migraine equivalents, 83 April 231.
**Lending, Robert E** pulmonary fibrosis, diffuse interstitial (Puzz Case), 83 March 63; was heart disease causing the cyanosis? 83 Nov 296.
**Lerner, Robert G** vitamin K deficiency (Puzz Case), 83 Oct 136.
**Levine, Robert S** childhood hypertension, diagnostic pitfalls, 83 June 225.
**Levy, Barry S** chemical poisoning in the workplace, 83 Nov 63.
**Lichstein, Jacob** gastric prolapse, 83 Sept 57.
**Lippe, Barbara M** brittle diabetes, 83 Jan 175.
**Localio, S Arthur** stoma management, 83 Feb 45.
**Lombardo, John A** arm injuries, 83 Oct 143.
**Louria, Donald B** superinfection (physicians' questions), 83 Nov 302.
**Lucchesi, Benedict R** myocardial preservation, 83 Feb 175.
**Lueg, Mark C** islet-cell adenoma (Puzz Case), 83 June 114; primary hyperparathyroidism (Puzz Case), 83 May 149.
**Mackowiak, Robert** workup for hypertension, 83 March 80.
**Maibach, Howard I** patch testing, 83 April 201.
**Mailloux, Lionel U** hypertension and renal disease, 83 Nov 97.
**Manning, Robert T** normal kidney function with hyperphosphatemia (Brf Consult), 83 Feb 269.
**Marpole, Derek GF** angiocardiography after MI, 83 March 224.
**Marsh, John C** lung cancer and headache, 83 Nov 143.
**Maxmen, Jerrold S** insomnia due to anesthetic? (Brf Consult), 83 June 45.
**McAuley, Bruce J** variant angina, 83 June 166.
**McCallum, Richard W** inflammatory bowel disease in adolescents, 83 Oct 37.
**McCarron, David A** hypertension and calcium, 83 Aug 212.
**McCrory, Wallace W** acute kidney failure, 83 March 167.
**Mead, Beverley T** adolescent homosexuality, 83 April 107.
**Mishell, Daniel R Jr** oral contraceptives, 83 April 139.
**Mitchell, Malcolm S** monoclonal antibodies, 83 May 127.
**Mohler, John G** editorial opinion: High cost of breathing (air pollution), 83 June 260.
**Mondini, Susanna** sleep disorders and arrhythmias, 83 July 193.
**Mooney, Al J III** alcoholism, 83 May 171.
**Moyer, Ray A** football and basketball injuries, 83 Nov 81.
**Mujais, Salim K** drug therapy with aging



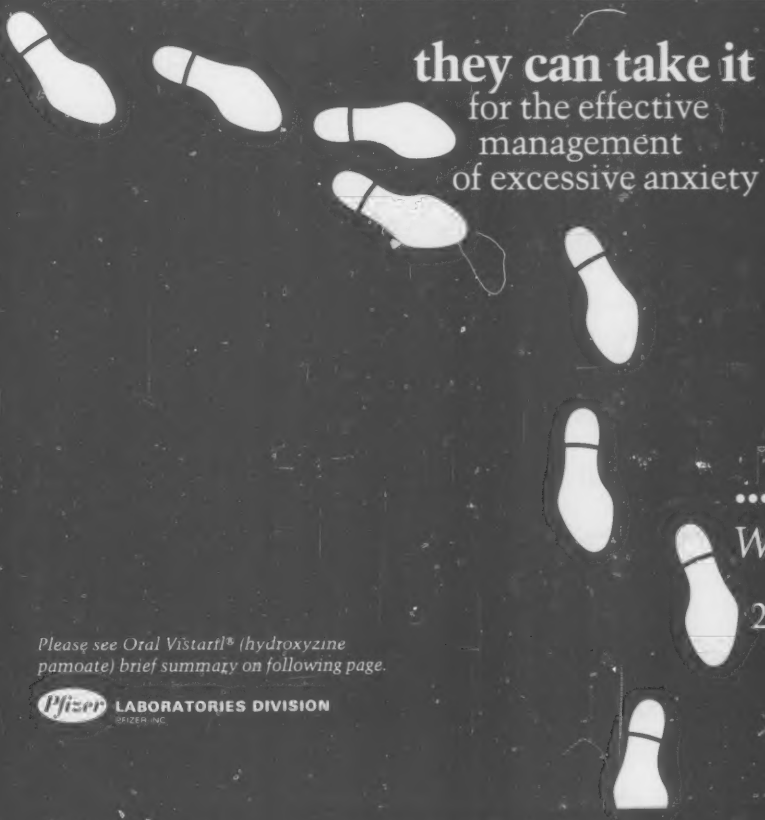

## YEAR-END INDEX

kidneys, 83 April 282.
**Murata, Stephen K** editorial opinion: Year of the serpent (health care costs), 83 Jan 330.
**Nash, David T** editorial opinion: Teach patients to ask 'why,' 83 Sept 262.
**Nestle, Marion** general nutrition, 83 Jan 271.
**Oh, William** neonatal jaundice, 83 Dec 51.
**Olson, O Charles** distinguishing true hypoglycemia from the myth, 83 Nov 35.
**Oparil, Suzanne** cardiovascular risks, women v men, 83 Feb 118.
**Orzeck, Eric A** what's new in blood glucose self-monitoring, 83 Aug 93.
**Oski, Frank A** neutropenia, 83 Jan 93.
**Owens, Donald W** atypical mycobacterial infections, 83 March 252.
**Palmer, Darwin L** antibiotics, which ones to stock in a hospital pharmacy? (Brf Consult), 83 Jan 241.
**Pantell, Robert H** febrile infants, 83 May 49.
**Panwalker, Anand P** cephalosporins, 83 June 244.
**Papadopoulos, Chris** postcoronary sexual problems, 83 April 303.
**Parry, Gareth J** diabetic neuropathies, 83 March 73.
**Pasterz, Robert** endocarditis (Puzz Case), 83 July 167; nephrotic syndrome (Puzz Case), 83 Oct 240.
**Patterson, William M** are tricyclics cardiotoxic? (Brf Consult), 83 Sept 249.
**Paulson, David F** bladder cancer, 83 Sept 151.
**Payne, Franklin E Jr** prescribing exercises for patients, 83 Aug 188.
**Pearson, Joanne M** counseling the dying child and family, 83 Sept 85.
**Phibbs, Brendan** endocarditis, 83 July 167; nephrotic syndrome (Puzz Case), 83 Oct 240.
**Pickering, Thomas G** stepped care really desirable for hypertension? 83 Oct 105.
**Prosser, Peterman R** diet therapy for diabetes mellitus, 83 Dec 29.
**Purcell, Elizabeth A** stoma management, 83 Feb 45.
**Raimer, Sharon S** topical steroids, 83 April 243.
**Ramsdell, Joe W** pulmonary function testing in office, 83 April 310.
**Raskind, Robert** labyrinthian disorder (Brf Consult), 83 March 181; roadside coma, 83 July 211.
**Rastogi, Shiva P** hypocalcemia, 83 July 92.
**Ratzan, Richard M** bites and stings from marine animals, 83 Aug 29.
**Ravdin, Jonathan I** diarrhea, infectious in pregnancy (Brf Consult), 83 March 145.
**Reid, William H** dreams of violence (Brf Consult), 83 March 109.
**Renshaw, Domeena C** ostomates and sex, 83 March 113.
**Rogers, Arvey** hormonally mediated diarrhea (Puzz Case), 83 April 69.
**Rosen, Ted** cutaneous hemangiomas, 83 Oct 289.
**Rosenberg, Allan J** oral rehydration for infantile diarrhea, 83 Oct 275.
**Roth, James LA** chronic hiccups (Brf Consult), 83 Oct 286.
**Ryan, Lawrence M** sacroiliitis, 83 Jan 127.
**Sackett, David L** patient compliance in hypertension, 83 Jan 287.
**Sarne, David H** thyroid neoplasms, 83 Sept 232.
**Sartor, R Balfour** ulcerative colitis (Brf Consult), 83 May 121.
**Scheidt, Stephen** beta-blockers for arrhythmias, 83 Feb 295.
**Scheinberg, Labe** multiple sclerosis (Puzz Case), 83 Jan 153.
**Searles, Robert P** systemic lupus erythematosus (Clinical Case No. 110), 83 Oct 252.
**Seidenfeld, John J** oxygen therapy for COPD (Clinical Case No. 102), 83 Feb 252.

## YEAR-END INDEX


**Selker, Harry P** Meckel's diverticulum (Clinical Case No. 108), 83 Aug 158.
**Sen, Purnendu** superinfection (physicians' questions), 83 Nov 302.
**Sharma, Om P** Kartagener's syndrome (Clinical Case No. 105), 83 May 232; Wegener's granulomatosis (Clinical Case No. 112), 83 Dec 124.
**Shea, Michael J** myocardial preservation, 83 Feb 175.
**Sherman, David E** cerebral stroke in a young man (Brf Consult), 83 April 265.
**Siegel, Frances** anemia, lab values in elderly (Brf Consult), 83 Feb 137.
**Smith, J Lacey** therapy for variceal hemorrhage, 83 Oct 86.
**Smith, Randall W** labyrinthian disorder (Brf Consult), 83 March 181.
**Stewart, R Malcolm** parkinsonism and tardive dyskinesia, 83 June 51.
**Stool, Sylvan E** otoscopy, 83 March 247.
**Strauss, Robert D** head and neck cancer (Clinical Case No. 111), 83 Nov 206.
**Stulbarg, Michael S** chronic bronchitis, 83 Sept 167.
**Stutchin AD** editorial opinion: Make a habit of treating addiction, 83 Oct 304.
**Subrt, Paul** topical steroids, 83 April 243.
**Sullivan, Timothy J** penicillin and rash (Brf Consult), 83 Feb 225.
**Talley, Joseph H** endogenous depression, 83 Feb 105; suicide prevention, 83 June 33.
**Taylor, D Wayne** patient compliance in hypertension, 83 Jan 287.
**Taylor, Robert B** aerobic exercise, 83 April 94.
**Teitelbaum, Daniel T** and **Teitelbaum, Sheila B** aspirin and acetaminophen overdose, 83 Feb 195.
**Thurman, Benjamin H** amitriptyline for chronic pain (Brf Consult), 83 Dec 94.
**Toskes, Phillip P** breath testing in GI and liver disorders, 83 Nov 117.
**Trauner, Doris A** neurologic examination of infants and children, 83 Nov 268.
**Tremper, Joyce C** oxygen therapy for COPD (Clinical Case No. 102), 83 Feb 252.
**Trice, Jill E** neurologic examination of infants and children, 83 Nov 268.
**Tyndall, Gary** ketoacidosis and hypoglycemia, 83 Oct 57.
**Udall, John N** nutrition in pregnancy, 83 July 170.
**Vaughn, Thomas C** fibrocystic breast disease, 83 June 129.
**Vyas, Girish N** viral hepatitis, 83 Sept 195.
**Walsh, Joseph B** hypertensive eye disease, 83 Sept 113.
**Waring, Nell P** JRA diagnosis, 83 May 93.
**Wassersug, Joseph D** editorial opinion: The little things that count, 83 Nov 312.
**Webster, Stephen B** pruritus ani, 83 Jan 311.
**Weiker, Garron G** manipulation of painful shoulder, 83 Dec 38.
**Weller, Peter F** amebiasis and giardiasis, 83 April 115.
**Wenger, Nanette K** lifestyle changes after MI, 83 Aug 111.
**Weston, William III** childhood poisoning, 83 Sept 250.
**White, Robert I** varicocele ligation (Brf Consult), 83 Sept 133.
**Whitehouse, Fred W** coma, diabetes, hypotension: management (Brf Consult), 83 April 147.
**Whiting, David A** current therapy for acne, 83 Nov 49.
**Wingert, Willis A** animal bites, 83 Feb 159.
**Winternitz, Sherry R** cardiovascular risks, women *v* men, 83 Feb 118.
**Wolf, Stewart** functional GI problems, 83 Aug 129.
**Wolinsky, Harvey** pulmonary edema (Puzz Case), 83 July 147.
**Wolk, Peter J** x-ray diagnosis of heart diseases, 83 Jan 195.
**Zion, Thomas E** childhood epilepsy management, 83 Jan 158.





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